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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,480	01/04/2002	Gregor Cevc	56822 (47126)	5210
21874	7590	09/20/2006	EXAMINER	
EDWARDS & ANGELL, LLP			FORTUNA, ANA M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1723

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,480

Applicant(s)

CEVC ET AL.

Examiner

Ana M. Fortuna

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6-8,35,60,61,66-69 and 102-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 3, 4, 6-8,35,60, 61, 66-69, 102-121- is/are rejected.
- 7) ☐ Claim(s) 36-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 3, 103-104 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 110-114 of copending Application No. 10/984,450.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. Claims 4, 6-8, 35, 60-69, 102-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 103-301 of copending Application No. 10/984,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 is a combination of claims 103-169, and 302-323 of the copending application.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3, 35, 60, 61-69, 107-121 are rejected under 35 U.S.C. 102(b) as being anticipated by Cevc (US patent 6165,500)(hereinafter reference '500). Reference '500 discloses the method as claimed in the claims above, including preparing the composition or penetrants, selecting a dose of the penetrants and passing the composition through pores of the membrane, e.g a microporous membrane, the pH of the formulation is also disclosed (abstract, column 1, first paragraph, column 4, lines 15-65, column 5, lines 22-49,). The amphiphilic substances are detailed (see column 8, lines 8, through column 19, first paragraph). The formulation pH ranges is selected to be between 3 to 12 (column 51, lines 27-42).

The adaptable membrane is disclosed in column 59, last paragraph, bridging column 60, lines 1-5, column 61, lines 21-49).

Limitation of claims 68, and 121 are disclosed (see claim 32, and column 52, lines 46-55). The use of the composition as claimed in claim 102 is disclosed (see column 1 first paragraph). Regarding 103-104, the pH is discussed above. The viscosity seems to be inherent of the surfactant and agent composition.

Limitation of claim 67 is disclosed in claim 22 of the patent:

Allowable Subject Matter

5. Claims 36-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The patch including the claimed composition and the liner as claimed in claim 36 and dependent claims is not disclosed or suggested in the prior art of record ad whole.

Response to Arguments

6. Applicant's arguments filed 6/28/06 have been fully considered but they are not persuasive. Applicant states that the claims in the double patenting rejection will be taken care after indication of allowable subject matter. The claims rejected under 101 have to be canceled in one of the copending applications, or amended. A terminal disclaimer needs to be filed to overcome the provisional obvious type rejection.

7. The rejection based on patent 6,165,500 is maintained. Applicant argues that patent '500 does not teach controlling the delivery of drugs through the skin or flux of penetrants, and does not suggest the relation between penetrants dose and flux of the penetrants (see response of 3/20/06, page 16, third paragraph).

The patent teaches the factors affecting the transport of agents through the permeation barriers, and recites the dose or concentration as playing an important role (column 49, lines 15-68, column 50, lines 1-24, column 50, lines 60-68, column 51, lines 1-1-2 and 20-26). For this reason the rejection is maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

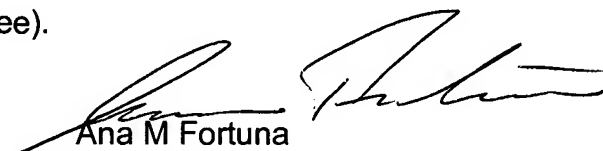
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ana M Fortuna
Primary Examiner
Art Unit 1723

AF

September 17, 2006